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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

KERR, KATHLEEN M

ART UNIT PAPER NUMBER

1652

DATE MAILED: 10/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/623,596

Applicant(s)

WACHI ET AL.

Examiner

Kathleen M Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,6-9 and 11-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8-14 is/are allowed.
- 6) ☒ Claim(s) 1-3,6,7 and 15-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/19/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application Status

1. In response to the previous Office action, a Final rejection (mailed on December 17, 2003), Applicants filed an amendment and request for continued examination (RCE) received on July 19, 2004. Said amendment amended Claims 1-3, 6, 7, and 17-19. Thus, Claims 1-3, 6-9, and 11-27 are pending in the instant Office action and will be examined herein.

A request for continued examination under 37 C.F.R. § 1.114, including the fee set forth in 37 C.F.R. § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. § 1.114, and the fee set forth in 37 C.F.R. § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R. § 1.114. Applicant's submission filed on July 19, 2004 has been entered.

Priority

2. As previously noted, the request for the benefit of priority for the International Application No. PCT/JP99/01084 filed on March 5, 1999 and the foreign application Japan 10-55608 filed on March 6, 1998, is noted. No translation of the JP document has been filed.

Information Disclosure Statement

3. The information disclosure statement filed on July 19, 2004 has been reviewed, and its references have been considered as shown by the Examiner's initials next to each citation on the attached copy.

Drawings

4. As previously noted, the drawings have been approved by the Draftsmen and are, therefore, entered as formal drawings acceptable for publication upon the identification of allowable subject matter.

Withdrawn - Claim Rejections - 35 U.S.C. § 112

5. Previous rejection of Claims 1-3, 6, 7, and 17-27 under 35 U.S.C. § 112, second paragraph, as being indefinite for being confusing as to which chromosomal PBP gene copies are to be affected is withdrawn by virtue of Applicant's amendment limiting to PBP3.

6. Previous rejection of Claims 2-3, 7, 21, 22, and 24 under 35 U.S.C. § 112, second paragraph, is withdrawn by virtue of Applicant's amendment clearly describing the relationship of the methods to temperatures.

7. Previous rejection of Claims 2 and 21 under 35 U.S.C. § 112, first paragraph, written description, is withdrawn by virtue of Applicant's amendment excluding mutations in PBP3 that are temperature sensitive mutations and relying on the temperature sensitive replicon in each case.

8. Previous rejection of Claims 2 and 21 under 35 U.S.C. § 112, first paragraph, enablement, is withdrawn for the same reasons as noted above for the withdrawal of the written description rejection.

Maintained - Claim Rejections - 35 U.S.C. § 112

9. Previous rejection of Claims 1-3, 6-7, and 17-27 under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for methods using coryneform bacteria with a reduced or eliminated PBP3 by virtue of a deletion, does not reasonably provide enablement for methods using coryneform bacteria with a reduced or eliminated PBP3 by virtue of a mutation other than deletion, is maintained. Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons.

Applicant argues that mutations, other than deletions, of enzymes are known in the art for the reducing and/or eliminating enzyme activity as evidenced by a frameshift mutation in the fimI gene to reduce its activity. This is not found persuasive because this frameshift is specific to the fimI gene and not relevant to the chromosomal copy of the PBP3 gene required to reduced or eliminated by mutation. The scope of the instant claim includes mutating the chromosomal copy of a coryneform PBP3 gene such that the PBP3 activity is lowered. No teachings of such mutants are exemplified, known in the art, or guided to by the instant application. As previously noted,

“While the state of the art is replete with examples of mutated proteins having reduced activity by virtue of a point mutation, such mutants protein-specific and cannot be correlated to the instant example without extensive information about structure relatedness. The ability to produce a reduced activity, non-deletion mutant PBP, similar to SEQ ID NO:2 is wholly unpredictable.”

For all these reasons, the instant rejection is maintained.

The Examiner notes that Claim 17 has been added to the instant rejection because the deletion limitation is specific for the plasmid DNA and not the chromosomal DNA, which is at issue here.

NEW ISSUES

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-3, 6, 7, and 17-27 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The nature of “a chromosomal gene of a penicillin binding protein 3 in coryneform” is confusing since only one is disclosed and the article “a” indicates any or more than one. If the single copy, as disclosed in the specification, is intended, the Examiner suggests ---the chromosomal gene--- for clarity. If multiple copies are intended, their nature is unclear as based on the disclosure (see Example 1). Clarification is required.

Moreover, the Examiner suggests ---the chromosomal gene encoding penicillin binding protein 3 (PBP3)--- and itemizing “mutating”, “transforming”, “cultivating” and “collecting” as (a), (b), (c), and (d) for clarity in Claim 1.

11. Claims 2 and 21 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In Claim 2, the phrases describing the first and second temperatures are unclear in their limitations of “not reduced or eliminated” since this language does not describe the plasmid whatsoever in Claim 1.

12. Claims 7 and 24 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

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applicant regards as the invention. In Claim 3, the phrase describing "the gene encoding the functioning penicillin binding protein 3" has no clear antecedent basis in Claim 1. The Examiner suggests ---the DNA--- for clarity as referred to in Claim 1.

13. Claims 17 and 25 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The scope of the claim is confusing. In Claim 1, the chromosomal copy of PBP3 is reduced or eliminated and "replaced" with the plasmid copy. But in Claim 17, this plasmid copy is also reduced or eliminated. PBP3 is disclosed as an essential gene to functioning bacteria so it is unclear how bacteria having reduced/eliminated PBP3 could be cultivated to produce glutamate. Clarification is required.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 1-3, 6, 7, and 17-27 are rejected under 35 U.S.C. § 112, first paragraph, new matter, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In Claim 1, the requirement of "an inducible promoter" on the plasmid that is used for transformation is not supported in the specification as originally

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filed. Plasmids are mentioned in pages 4-5 on page 17 as containing a PBP gene and a temperature sensitive replication control region. Inducers are mentioned on page 10, but not in conjunction with plasmids.

Specifically for Claim 1, the absence of the temperature sensitive replicon limitation is considered new matter. While the specification teaches the essence of controlling PGP3 expression, because it is required for growth yet inhibitory in the production of glutamate, the breadth of Claim 1 is not described. This is also the case for Claim 2, which does not require the temperature sensitive replicon (and dependent Claims 6, 17-22 and 24-27).

15. Claims 15-16 are rejected under 35 U.S.C. § 112, first paragraph, new matter, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims to generic "bacterial cells" comprising the vectors of Claims 13-14 are not supported in the specification as originally filed. Vectors are supported, for example on page 13. However, the genus of "bacterial cell" as harboring said vectors is not disclosed.

Summary of Pending Issues

16. The following is a summary of the issues pending in the instant application:
- a) Claims 1-3, 6, 7, and 17-27 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the nature of "a chromosomal gene of a penicillin binding protein 3 in coryneform".
 - b) Claims 2 and 21 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrases describing the first and second temperatures.
 - c) Claims 7 and 24 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the antecedent basis of "the gene encoding the functioning penicillin binding protein 3".

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- d) Claims 17 and 25 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the claimed scope.
- e) Claims 1-3, 6, 7, and 17-27 stand rejected under 35 U.S.C. § 112, first paragraph, new matter.
- f) Claims 15-16 stand rejected under 35 U.S.C. § 112, first paragraph, new matter.
- g) Claims 1-3, 6-7, and 17-27 stand rejected under 35 U.S.C. § 112, first paragraph, scope of enablement (enabled for deletion but not mutation in general).

Allowable Subject Matter

17. As previously noted, Claims 8 and 9 are considered free of the prior art. The closest prior art was noted in the previous Office action as Cole *et al.* teaching a *M. tuberculosis* gene encoding a “probably penicillin binding protein”. The structural similarities between the *M. tuberculosis* gene and SEQ ID NO:1 are outside the metes and bounds of Claims 8 and 9.

Conclusion

18. Claims 8, 9, and 11-14 are allowed; Claims 1-3, 6, 7, and 15-27 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (571) 272-0931. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen M Kerr
Primary Examiner
Art Unit 1652

October 13, 2004